

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CRIMINAL No.
09-10330-GAO

UNITED STATES OF AMERICA

v.

STRYKER BIOTECH, LLC
MARK PHILIP, WILLIAM HEPPNER,
DAVID ARD and JEFFREY WHITAKER

**ORDER ON DEFENDANTS' JOINT MOTION
FOR DISCLOSURE OF EXCULPATORY INFORMATION**

May 25, 2010

DEIN, M.J.

This matter is before the court on Defendants' Joint Motion for Disclosure of Exculpatory Information (Docket No. 42). At oral argument, the motion was limited to Defendants' request for "information about off-label use of, and adverse events regarding, products that compete with the Stryker Biotech products at issue in this case (OP-1 and Calstrux) that is contained in investigative files of the prosecution team in this case or in files in other investigations known by the prosecution team in this case." (Docket No. 42 at 2, ¶ 1). After consideration of the parties' written submissions, including the Defendants' post-hearing Reply, as well as the oral arguments of counsel, the motion is DENIED.

The Parties' Positions

The Defendants are charged with mail and wire fraud, conspiracy both to defraud the FDA of its lawful regulatory authority to ensure the safety of medical

devices in humans, and to commit the substantive crime of misbranding, and misbranding. The crux of the Indictment is the charge that the Defendants “fraudulently promoted and caused the fraudulent promotion of OP-1 for off-label uses, including the mixture of OP-1 and Calstrux which was a use not approved by the FDA and not clinically tested in humans.” (Gov’t Response (Docket No. 45) at 5). The Defendants contend that Stryker Biotech’s competitor, Medtronic, marketed the product INFUSE, which they describe as “the only commercially available bone morphogenetic protein other than Stryker Biotech’s OP-1 products[.]” (Defs. Reply (Docket No. 51) at 1). Based on publicly available information, the Defendants contend that surgeons frequently used Medtronic’s product for an off-label use by “mixing INFUSE with the tri-calcium phosphate product Mastergraft, an analogue to the OP-1/Calstrux mixing technique that is at the center of the indictment.” (Id.). Information about such off-label use of Medtronic’s product, according to the Defendants, is exculpatory because “[t]o the extent that Defendants can show pervasive off-label use of competing products, it undermines the government’s argument that the Defendants unlawfully induced off-label use that otherwise would not have occurred, as well as the notion that the Defendants had a motive to engage in such concealment in order to gain competitive advantage.” (Defs. Mem. (Docket No. 43) at 5). Moreover, according to the Defendants, such information is exculpatory on the issue of patient harm because “[t]o the extent that Defendants can show that adverse events and other problems are unavoidably inherent in the use of all similar products, the government’s argument withers away.” (Id. at 6). Finally, the Defendants argue, “[e]vidence of off-label use of

competing products will also shed light on whether the Defendants complied with FDA guidance” because “[s]urgeons’ pervasive off-label use of all [bone morphogenetic proteins] supports the defense that the Defendants and other Stryker employees were permissibly responding to physicians’ unsolicited requests for off-label information, not initiating such discussions.” (Id.).

For its part, the Government opposes the production of the requested information on the grounds that it is a “fishing expedition.” (Gov’t Response (Docket No. 45) at 1). The Government has produced everything in the prosecution team’s file in this case regarding off-label use and adverse events of competing products, but has declined to produce information which may be contained in files of other investigations about which the prosecution team may be aware. (Id.).¹ The Government contends that information concerning off-label use and adverse events of competing products would not be exculpatory for a myriad of reasons. After consideration of all the arguments raised by both parties (even if not addressed herein), this court finds the Government’s arguments persuasive, and the motion for disclosure is denied.

Discussion

¹ The Government has not admitted or denied the existence of an ongoing investigation into Medtronic. The Defendants claim to be aware of such an investigation from public information, and assert they are willing to limit their request, at this time, to summary information regarding the off-label use of INFUSE, as well as redacted grand jury transcripts, interview reports or other recordings of witness’ statements. (Defs. Reply (Docket No. 51) at 7-8). They are also willing to abide by confidentiality restrictions. (Id. at 8). However, as detailed herein, this court finds no basis for the disclosure of this information, even without considering any impact on an ongoing investigation that the production of this material may have.

As an initial matter, the Government argues that FDA approval of Stryker Biotech's products was much more limited than the approvals obtained by Medtronic. (See Gov't Response (Docket No. 45) at 3-4). Consequently, according to the Government, INFUSE was not a competing product for OP-1. (Id. at 9-10). The Defendants argue that while the approvals may have been different, "*in practice*, orthopaedic surgeons view INFUSE and OP-1 as the two competing options when treating a patient with a bone morphogenetic protein, and the products' label indications do not necessarily dictate which option the surgeon chooses." (Def. Reply (Docket No. 51) at 6). The Defendants' argument, however, begs the question. If the products were not, in fact, approved for the same uses, but the Defendants knew they were being used interchangeably, if anything this would increase the burden on the Defendants to make sure that the doctors were aware of the differences. In any event, the issue comes back to what the Defendants knew and why they acted the way they did. Information about the off-label use of non-competing products would not be exculpatory.

More fundamentally, this Court does not find persuasive the Defendants' argument that evidence to the effect that off-label mixing of Medtronic's product was generally accepted is exculpatory to the charges brought against the defendants in this case. Contrary to the Defendants' claim, such information simply does not go to the issue of whether the Defendants acted with criminal intent when they made representations to the FDA or when they marketed the OP-1 products with knowledge of the limited uses approved by the FDA. All of the connections the Defendants are seeking to make are simply too tenuous.

For example, the Defendants claim that “the fact that well-informed orthopaedic surgeons have routinely used INFUSE off-label as a matter of well-established, good medical practice (and before either OP-1 or Calstrux was introduced to the market) refutes the Government’s suggestion that surgeons needed to be *tricked* or *deceived* into using OP-1 off-label” and “demonstrates that the Defendants had no economic motive to engage in the alleged scheme to defraud doctors.” (Defs. Reply (Docket No. 51) at 2). However, the fact that surgeons may have used another company’s product for off-label uses does not, in this Court’s view, logically lead to the conclusion that they would have automatically used the different Stryker Biotech’s product without the intentional intervention of and/or dissemination (or withholding) of information by the Defendants. Similarly, even if some doctors may have mixed OP-1 without any prodding by the Defendants, the Defendants clearly still would have an economic motive in insuring that others did so as well.

The Defendants also argue that the widespread off-label use of INFUSE refutes the Government’s suggestion that the off-label use of OP-1 was due to an underlying scheme to defraud doctors, “rather than the result of doctors’ independent and well-informed decisions to do what they viewed as best for their patients.” (*Id.*). Again, however, what the doctors knew about INFUSE does not explain how or why they used a different product which had different FDA approvals. In fact, it is difficult to understand how the Defendants can assert that the use of INFUSE off-label is evidence that the doctors were making a “well-informed” decision about OP-1 given the differences in

the products and the fact that the Government is asserting (and must prove) a failure to disclose relevant information.

Similarly unsupportable is the Defendants' argument that evidence that doctors had experience mixing INFUSE, although it was an off-label use, and were aware that such mixing had not been studied in humans and sometimes had adverse consequences, bears on whether the Defendants had a motive to conceal from doctors similar information regarding OP-1 and Calstrux. (Defs. Reply (Docket No. 51) at 4). Thus, the Defendants contend, "if Defendants thought or believed that doctors were already aware of the information regarding OP-1 and Calstrux that the Government alleges was not disclosed to doctors, this would also strongly support a good faith defense, *i.e.*, that any such failures to disclose on the part of the Defendants' were not done with the requisite fraudulent intent." (*Id.*). Again, however, in light of the different approvals, the doctors' knowledge about Medtronic's products cannot be extrapolated to the OP-1/Calstrux situation. The fact that some doctors may have been aware that there were risks in mixing INFUSE simply does not lead to the conclusion that doctors would blindly mix other products as well, so that the Defendants would understand that they did not have to disclose known risks. In short, these arguments are unpersuasive and the links the Defendants are trying to make are unsupported.

The Defendants' arguments fail for the additional reason that they distort the focus of the Government's claims of wire fraud, conspiracy to defraud and misbranding. The "relevant inquiry is whether there was an intent to mislead the victim by inducing an uninformed consent to part with money or property." United States v. Allard, 926

F.2d 1237, 1242 (1st Cir. 1991). “It is not necessary to establish that the intended victim was *actually* defrauded.” *Id.* As the Government argues, “[t]hese crimes focus on defendants’ intent, and that intent and participation cannot reasonably be affected by some doctors’ use of, and experience with, a product other than OP-1 and Calstrux.” (Gov’t Opp. (Docket No. 45) at 12).

Conclusion

In sum, even assuming they were competitive, OP-1 and Calstrux were simply different products than INFUSE/Mastergraft. They had different approvals from the FDA and were to be used for different purposes. The information known to these Defendants, and the actions undertaken by these Defendants, are the controlling issues. Whether or not Medtronic’s products were generally mixed in an off-market use does not constitute exculpatory evidence as to the pending charges. The motion for disclosure is DENIED.

/ s / Judith Gail Dein
JUDITH GAIL DEIN
United States Magistrate Judge